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Advent Pharmaceuticals, Inc.	:	UNITED STATES BANKRUPTCY COURT
	:	FOR THE DISTRICT OF NEW JERSEY
	:	
Debtor.	:	CHAPTER 11
	:	
	:	CASE NO. 11-25437
	:	

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**Objection to Motion of Debtor to Sell Ibuprofen ANDAs**

UPS Capital Business Credit, a secured creditor of Debtor (“UPSCBC”) submits this filing in opposition to the motion [Docket entry 80] of Debtor Advent Pharmaceuticals, Inc. (“Advent”) to sell abbreviated new drug application number 076460 relating to the marketing of ibuprofen 200 mg tablets and 200 mg caplets (the “ANDAs”) to BioComp Pharma, Inc. for \$750,000.00 (the “Application”). As has been addressed in the papers put before the Court on UPSCBC’s prior motion to dismiss the Advent bankruptcy, and as are again addressed below, the ANDAs are no longer assets of Advent, having been sold by UPSCBC as secured party prior to the filing of the bankruptcy proceeding. Accordingly, Advent does not own and therefore cannot sell the ANDAs, and the Application must be denied.

**Claims and Liens of UPSCBC**

The claims and liens of UPSCBC have been put before this Court several times in evidential form [Docket entries 12, 38 and 39]. The Court recognized the claims and liens of UPSCBC in the entry of the Order for the sale of 55 Lake Drive and the equipment of Debtor

Advent [Docket entry 75]. However for purposes of completeness, those claims and liens are again reprised as follows:

Advent is indebted to UPSCBC under Notes dated December 21, 2000, December 29, 2000 and June 15, 2001. [Certification of Brian Rice, par. 3] As a portion of the collateral security for the obligations evidenced by those Notes, Advent executed and delivered Security Agreements dated December 29, 2000, March 1, 2001 and June 15, 2001 (the “Security Agreements”), granting UPSCBC security interests in assets of Advent including, for purposes of this motion, Advent’s general intangibles. [Certification of Brian Rice, par. 5]. UPSCBC’s security interests were perfected by the filing of numerous UCC-1 financing statements with the New Jersey Department of the Treasury. [Certification of Brian Rice, par. 5].

#### **Objection to Advent’s Application**

The New Jersey Uniform Commercial Code defines a “general intangible” as “any personal property, including things in action, other than accounts, chattel paper, commercial tort claims, deposit accounts, documents, goods, instruments, investment property, letter-of-credit rights, money, and oil, gas, or other minerals before extraction.” N.J.S.A. 12A:9-102(42). As is implicit in the definition, under the structure of the Uniform Commercial Code, a “general intangible is the residual category of personal property . . . that is not included in other defined types of collateral.” N.J.S.A. 12A:9-102, Uniform Commercial Code Comment 5(d).

An abbreviated new drug approval is the right of a party, as granted by the United States Food and Drug Administration (the “FDA”), to market a drug that is the same in all material respects as a drug has previously been approved by the FDA. 21 C.F.R. 314.92. As will be discussed in more detail below, an ANDA is transferrable by its owner. 21 C.F.R. 314.72(a).

Under the broad catchall definition of the Uniform Commercial Code, abbreviated new drug approvals are general intangibles.

Advent defaulted in the payment and performance of its obligations to UPSCBC under the loans evidenced by the Notes, resulting in the entry of judgment in favor of UPSCBC in a contested state court action. [Certification of Jay Samuels, par. 4]

Pursuant to the rights granted to UPSCBC under N.J.S.A. 12A: 9-610(a)<sup>1</sup> and under the Security Agreements, UPSCBC undertook the steps required to sell the ANDAs by private secured party sale. Notice of the private secured party sale, in accordance with the requirements of N.J.S.A. 12A:9-613, was given by UPSCBC to (among others) Advent, Bharat Patel, Pragna Patel and Siddhartha Dubal, then-attorney for Advent. [Certification of Jay Samuels, par 5]. The Notice of Private Sale was sent to Advent, and to Bharat Patel and Pragna Patel at their home address at 10 Buckingham Drive, East Brunswick, New Jersey by certified mail and by regular mail. [Certification of Shanti Durga, pars. 2, 3]. The certified mail Notices were returned unclaimed. The regular mail Notices were not returned. [Certification of Jay Samuels, par. 7]

Additionally, the Notice of Private Sale was sent by regular mail, fax and email to Siddhartha Dubal, Esq. the attorney then representing Advent. [Certification of Jay Samuels, par. 8]. There can be no material disagreement that Advent received the notice of sale, as Advent responded to the same with a letter dated March 1, 2011.<sup>2</sup> [Certification of Jay Samuels, par. 9].

Notice of sale having been given to the Debtor, “A secured party’s disposition of collateral after default transfers to a transferee for value all of the debtor’s rights in the

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<sup>1</sup> “After default, a secured party may sell, lease, license or otherwise dispose of any of its collateral . . . .”

<sup>2</sup> Substantively, that letter had no effect. Advent’s only right under the Uniform Commercial Code would have been to redeem by making payment in full to UPSCBC. N.J.S.A. 12A:9-623.

collateral.” N.J.S.A. 12A:9-617(a)<sup>3</sup>. The purchaser of the ANDAs, PLD Acquisitions, LLC (“PLD”) paid the UPSCBC the sum of \$650,000.00 for the transfer of the ANDAs [Certification of Brian Rice, par. 7], and is a transferee for value.

Here the analysis would end but for the need to clarify certain matters relating to the FDA. However, as will be established below, these matters do not change the outcome that the ANDAs have been sold and Advent has no further rights in them.

The FDA regulations establish beyond peradventure that ANDAs are freely transferrable between private parties, without the requirement of any prior or subsequent consent or approval of the FDA. 21 C.F.R. 314.72(a)<sup>4</sup> plainly states that “an applicant<sup>5</sup> may transfer ownership of its application.” At the time of transfer the new and former owners are required to submit certain information to the FDA. Specifically, the Regulations state that “The ***former owner*** shall submit a letter or other document that states that all rights to the application have been transferred to the ***new owner***.” 21 C.F.R. 314.72(a) (emphasis added). The new owner is to submit to the FDA certain information including “***the date the change in ownership is effective.***” 21 C.F.R. 314.72(a)(2)(ii) (emphasis added). The fact that the FDA has provided by Regulation that the parties to a transfer of an ANDA will tell the FDA when the transfer is effective, together with the Regulation’s use of the term “former owner” in the present tense, can leave no doubt that the

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<sup>3</sup> Although UPSCBC does not believe that the issue is in any way implicated, it notes that N.J.S.A. 12A:9-617(b) protects the ownership rights of a good faith transferee from a secured party.

<sup>4</sup> The subject of change of ownership of an ANDA is addressed by the FDA Regulations only in 21 C.F.R. 314.72 and by the redundant statement in 21 C.F.R. 314.99(a) that an applicant shall comply with the requirements of 21 C.F.R. 314.72 regarding a change in ownership of an abbreviated application.

<sup>5</sup> An “applicant includes “any person ***who owns*** an abbreviated application.” 21 C.F.R. 314.3 (emphasis added).

applicant has the independent power to transfer an ANDA without either prior notice to or the prior consent of the FDA.<sup>6</sup>

Not surprisingly, since ANDAs are freely transferable, neither 21 C.F.R. 314.72 nor any other FDA Regulation address the creation or enforcement of security interests in an ANDA, including the subject of transfers of an ANDA by a secured party of an ANDA owner in enforcement of a security interest. As such, these subjects are properly governed by the Uniform Commercial Code as applicable nondiscriminatory state law. United States v. Kimbell Foods, Inc., 440 U.S. 715, 728-733 (1979).

All of the foregoing being the case, the FDA has no role in determining ownership of the ANDAs. The FDA publishes what is referred to as the “Orange Book,” which lists “Approved Drug Products with Therapeutic Equivalence Evaluations.”<sup>7</sup> The Orange Book includes a listing of application holders. However these listings are informational, and are no way substantive or, as the courts have phrased it, “purely ministerial”. Compare AAIPharma v. Thompson, 296 F.3d 227, 241-242 (4<sup>th</sup> Cir. 2002) (addressing the effect of patent information listings in the Orange Book, stating that the “certification scheme is to let private parties sort out their respective intellectual property rights through patent infringement suits while the FDA focuses on its primary task of ensuring that drugs are safe and effective. This division of labor is appropriate

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<sup>6</sup> Certainly when Congress or a federal agency wishes to circumscribe the ownership or free transferability rights of an approval or license issued by the agency, it knows how to do so. Compare, e.g., the statute which governs licenses issued by the Federal Communications Commission:

**47 USC 310(d) Assignment and transfer of construction permit or station license**  
No construction permit or station license, or any rights thereunder, shall be transferred, assigned, or disposed of in any manner, voluntarily or involuntarily, directly or indirectly, or by transfer of control of any corporation holding such permit or license, to any person except upon application to the Commission and upon finding by the Commission that the public interest, convenience, and necessity will be served thereby.

<sup>7</sup> <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>

because *the FDA has no expertise in making patent law judgments.*" (emphasis added);

Apotex, Inc. v. Thompson, 347 F.3d 1335, 1347 (Fed. Cir. 2003) (same).

The situation is no different with respect to ownership of ANDAs. There are no Regulations which even so much as suggest that the Orange Book is a registry system, that the FDA has or claims any expertise in making ownership determinations, or that the FDA's listings of applicants in the Orange Book are substantive determinants of the rights of the parties to ownership of an abbreviated new drug approval. The specific regulations of the FDA on ownership and transfer of abbreviated new drug approvals, detailed above, conclusively negate any such construction.<sup>8</sup> Thus, transfer of the ownership of the ANDA was complete when UPSCBC delivered the secured party Bill of Sale for the ANDA to PLD.

Assuming, for the purposes of argument, that reflection of a party's ownership in the "Orange Book" is somehow substantive rather than informational/ministerial, the Uniform Commercial Code addresses the precise issue where a registry system is in place to reflect ownership and the record owner's consent is nominally required by the applicable regulatory scheme to reflect a transfer of ownership of an asset which is collateral for a secured claim. N.J.S.A. 12A:9-619 provides that a secured party may issue a "transfer statement," and that the transfer statement "entitles the transferee to transfer of record all rights of the debtor in the collateral specified in the statement in any official filing, recording, registration or certificate-of-title system covering the collateral." N.J.S.A. 12A:9-619(b). Upon presentation of the transfer statement, the official or office responsible for maintaining the registry system *shall* accept the transfer and promptly amend its records to reflect the transfer. Id., (emphasis added).

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<sup>8</sup> As a purely informational matter, the Orange Book available on-line on September 22, 2011 lists PLD (Avema), and not Advent, as the owner of the ANDAs. [Certification of Jay Samuels, par. 11].

In this matter, a functional transfer statement, in the form consistent with FDA form used in the case of transfers by owners, was issued by UPSCBC, and was delivered by UPSCBC to PLD. [Certification of Brian Rice, par. 9]. On or about March 21, 2011, the statement was delivered by PLD to the FDA, together with the information required of a new owner pursuant to 21 C.F.R. 314.72(2). [Certification of Dana S. Toops, par. 4]. The FDA actually received the materials so provided, and in fact changed its records to reflect the transfer. [Certification of Evan Singer, par. 9]<sup>9</sup>

However, it must be emphasized that the relevant act effecting the transfer of ownership of the ANDAs was not the reflection of the transfer in the FDA Orange Book, or any other action of the FDA, but the transfer at the secured party sale, evidenced by the Bill of Sale from UPSCBC to PLD. [Certification of Brian Rice, par. 8] This, again, follows from the structure of 21 C.F.R. 314.72, and the absence of any regulation of security interests in abbreviated new drug approvals other than the generally applicable requirements of the Uniform Commercial Code. In no case was consent of or action by Advent required for the transfer of the ANDAs via the private secured party sale to PLD to be effective. All that was required was compliance with Article 9. This, after all, is the entire point of Part 6 of Article 9 of the Uniform Commercial Code. Any contrary position somehow requiring debtor consent to or approval of a secured party's remedies eviscerates the rights of secured parties.

Nor, as shown above, was any or consent of or action by the FDA required for the transfer to be effective. The new owner (PLD) promptly provided the FDA with information required of new owners of abbreviated new drug approvals generally. Accordingly, the secured party sale of the ANDA was effective as of March 17, 2011, cannot be set aside by the Debtor

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<sup>9</sup> The Singer Certification is being filed by PLD in response to the Debtor's Application to sell the ANDAs.

Advent, and cannot be affected by actions or inactions of the FDA. United States v. Whiting Pools, Inc., 462 U.S. 198, 211, 103 S. Ct. 2309, 2316-17 (1983). Thus the Ibuprofen ANDAs are not property of the estate, and cannot be sold by Advent pursuant to 11 U.S.C. 363(b).

Additionally, should the foregoing for some reason not be dispositive, under 11 U.S.C. 363(f), Advent cannot sell the ANDAs without the consent of UPSCBC. The present proposed sale price for the ANDAs is for \$750,000.00, which is far below the lien of UPSCBC, which exceeds \$4,500,000.00.<sup>10</sup> Nor, it should be noted, would the proposed sale of the ANDAs have any particularly material beneficial effect for Advent. The UPSCBC secured party sale of the ANDAs to PLD resulted in a sale price of \$650,000.00, which, except for a cost reserve, was applied against obligations of Advent. [Certification of Brian Rice, par. 10]. Advent has already admitted its inability to reorganize. There is no legal basis for Advent to sell the ANDAs, or to upset the prior sale to PLD, and such action will, in any event, have no practical effect for Advent.

#### Cross-Motion of UPSCBC

To the extent Advent continues to claim ownership of or rights in the ANDAs, including by virtue of the adversary proceeding 11-2283 commenced by Advent against UPSCBC and PLD,<sup>11</sup> UPSCBC requests an Order from this Court to address the following issue: In connection with the sale of the ANDAs to PLD, at the request of PLD and in accordance with its obligations under the Agreement for Private Secured Party Sale between UPSCBC and PLD, UPSCBC filed UCC-3 releases of the ANDAs from UPSCBC's security interests. [Certification of Jay Samuels, par. 12]. To the extent that the private sale transaction is undone and rights to the ANDAs are

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<sup>10</sup> The Court should be made aware that the proposed buyer of the 55 Lake Drive property and equipment of Advent, which was the subject of this Court's Order dated August 17, 2011, is refusing to close and has requested the return of its deposit. [Certification of Jay Samuels, par. 10]

<sup>11</sup> With respect to which UPSCBC expects to have a motion for summary judgment filed by the return date of the hearing on the Application.

found to continue to exist in Advent<sup>12</sup>, for the status quo ante to be restored, the ANDAs must remain subject to the security interests of UPSCBC. To this end, the Court should enter an Order deeming the UPSCBC security interest in the ANDAs to be fully perfected in such event, and allowing UPSCBC the ability to file UCC financing statements with respect to the ANDAs in such event. 11 U.S.C. 105(a).

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<sup>12</sup> Which UPSCBC has shown, above, cannot and should not be the case.

**Conclusion**

For all of the foregoing reasons, Debtor's Application should be denied, and UPSCBC's cross-motion should be granted.

Respectfully submitted

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By: \_\_\_\_\_/s/ \_\_\_\_\_  
Jay Samuels

Dated: September 26, 2011